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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/596,062 | 06/20/2007 | Yang Liu | 22727/04398 | 1364 |

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| EXAMINER | |
|---|---|
| MYERS, CARLA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/11/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/596,062 | LIU ET AL. | |
| | Examiner | Art Unit | |
| | Carla Myers | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**Election/Restrictions**

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-5, 6, 8 and 17 (in part), drawn to methods for predicting the likelihood that an individual with develop multiple sclerosis by assaying for a mutation at position 226 of the nucleic acid encoding CD24.

Group II, claims 2, 3-5, 9 and 18 (in part), drawn to methods for predicting the likelihood that an individual with develop multiple sclerosis by assaying for a mutation at position 1110 of the nucleic acid encoding CD24.

Group III, claim 7 (in part), drawn to methods for predicting the likelihood that a subject diagnosed with multiple sclerosis will experience rapid progression of multiple sclerosis by assaying for a deletion of nucleotides 1580 and 1581 in the nucleic acid encoding CD24.

Group IV, claims 10 and 12-16 (in part), drawn to methods for predicting the likelihood that an individual with develop multiple sclerosis by assaying for the level of cell surface expression of CD24, wherein an increase in expression of CD24 is correlated with the presence of a thymidine at position 226 of the nucleic acid encoding CD24.

Group V, claims 11 and 12-16 (in part), drawn to methods for predicting the likelihood that an individual with develop multiple sclerosis by assaying for the level of cell surface expression of CD24, wherein an increase in expression of CD24 is correlated with the presence of a guanine at position 1110 of the nucleic acid encoding CD24.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the claimed inventions do not share a linking technical feature because each of the claimed methods involve the use of different reagents, have different outcomes and different effects. The methods of inventions I-III require detecting the presence of polymorphisms that differ from one another with respect to their nucleotide identity and location in the CD24 gene, and with respect to their biological activity and effect. Thus, the different polymorphisms of Groups I-III do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature." Further, the methods of Groups IV and V differ from the methods of Groups I-IIII in that the methods of Groups IV and V require determining the level of surface expression of CD24 protein on test cells and control cells. This step is not required to perform the methods of Groups I-III. the methods of Groups IV and V have a different mode of operation and effect and do not share the same or corresponding technical feature with the methods of Groups I-III. It is noted that the methods of Groups IV and V both require determining the level of expression of CD24 on the surface of a test cell and a control cell. However, the method of Group IV recites that an increase in the level of expression of CD24 indicates that there is a thymidine at position 226 of the gene encoding for CD24, while the method of Group V recites that an increase in the level of

expression of CD24 indicates that there is a guanine at position 1110 of the gene encoding for CD24. Accordingly, the effects and objectives of the methods of Groups IV and V are different from one another. Given that the recited polymorphisms differ from one another with respect to their nucleotide identity, location and functional activity, the polymorphisms recited in Groups IV and V also do not share both a common structure and function as is required to establish that they are of the same nature. Further, the technical feature linking the different inventions of the CD24 gene and its association with MS was known in the art at the time the invention was made. For example, Bai et al (Journal of Clinical Investigation. 2000. 105: 1227-1232) teaches that deletion of CD24 (also referred to as HAS) and the absence of expression of CD24 is correlated with experimental autoimmune encephalomyelitis, which is a model for human multiple sclerosis (page 1231). Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634